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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,625	02/11/2002	Joseph R. Lakowicz	UMARYI	4325
23373	7590	10/25/2005	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 10/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/073,625

Applicant(s)

LAKOWICZ, JOSEPH R.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/28/05</u> , <u>11/18/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 11/18/2004 has been entered.

The claims 28-82 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 28-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 28-82 are vague and indefinite because of the phrase "biomolecules". It is unclear what is the definition of the phrase in the specification.

b. Claims 28-82 are vague and indefinite because of the phrase "electromagnetic radiation". It is unclear what is encompassed by the phrase.

c. Claims 28-82 are vague and indefinite because it is unclear what is meant by the phrase "an extrinsic fluorescent marker is not a part of the system". Moreover, it is unclear what is definition of "an extrinsic fluorescent marker". Clarification is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 28-32, 37-43 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kummerlen et al. (Molecular Physics, 1993, Vol. 80(5), pg. 1031-1046).

Kummerlen et al. disclose enhancement of Fluorescence intensity. The dye film is brought into the proximity of the island film support. The resonant excitation phenomenon due to collective action of the islands (See pg. 1031, the Abstract). The situation of a silver island film is consisted of many individual metal spheroids (See pg. 1032, second paragraph). The excitation wavelengths are 514nm, 488nm and 458nm (See pg. 1033, forth paragraph). The dye is deposited on top of the quartz layer (See pg. 1033, third paragraph). Maximum enhancement is observed for distance around 60-70nm (See pg. 1038, last paragraph).

Since the phrase “biomolecules” was not defined, any molecule is interpreted as biomolecule. The teachings of Kummerlen et al. anticipate the limitations of claims.

6. Claims 46-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Lakowic et al. (WO 99/36779, issued July 22, 1999).

Lakowicz et al. disclose an assay in which a metal-ligand complex is used to bring into interactive proximity with the sample containing the analyte of interest. The mixture is irradiated with electromagnetic light energy to emit the light, which indicates the analyte of interest (See the Abstract and pg. 6, lines 16-24). The metal complex is a DPPG labeled vesicles (See pg. 12,

Art Unit: 1637

lines 21-26). The metal-ligand complex is conjugated to human serum albumin (HSA) (See pg. 8, lines 6-8). The distance of the metal complex is 10 to 120 Å with the sample (See pg. 6, lines 16-24). Human serum albumin (HSA) is considered as a second biomolecule and is covalently linked to the metal (See column 21, lines 5-15). The ligand is carbon monoxide (See pg. 54, lines 17-21). Lakowicz et al. further disclose that the assay is used to quantify the analyte of interest in which a first binding partner and a second binding partner are added to the sample, the first binding partner competes with the analyte to binding to the second binding partner, the first or second binding partner is labeled with a metal-ligand complex and the other is labeled with a photoluminescent energy transfer acceptor wherein the metal-ligand complex and photoluminescent energy transfer acceptor are chosen, when the first binding partner binds to the second binding partner, the metal-ligand complex and the photoluminescent energy transfer acceptor are brought in interactive proximity, producing a detectable change in luminescence (See pg. 53, lines 6-21). The metal-ligand complex typically absorb above 550 nm (See pg. 22, lines 20-22).

The teachings of Lakowicz et al. do not specifically indicate that there is a composition disclosed. However each element of the composition of claims 67-82 is read on the teachings of the features of the metal-ligand complex and the method of using the metal-ligand complex (See pg. 11-15). Thus, the teachings of Lakowicz et al. anticipate the limitations of the claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1637

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 33-36 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kummerlen et al. (Molecular Physics, 1993, Vol. 80(5), pg. 1031-1046) as applied to claims 28-32, 37-43 and 45 above, and further in view of Lakowicz et al. (WO 99/36779, issued July 22, 1999).

The teachings of Kummerlen et al. are set forth in section 5.

The teachings of Kummerlen et al. do not disclose second biomolecule is attached to one or more metal particles and intrinsic emission of electromagnetic radiation of at least one of one or more second biomolecules is affected by the exposing the system to exciting electromagnetic radiation and the second biomolecule is a member selected from the group consisting of a nucleotide, protein and lipid.

The teachings of Lakowicz et al. are set forth in section 6 above.

Lakowicz et al. further disclose that the assay is used to quantify the analyte of interest in which a first binding partner and a second binding partner are added to the sample, the first binding partner competes with the analyte to binding to the second binding partner, the first or second binding partner is labeled with a metal-ligand complex and the other is labeled with a photoluminescent energy transfer acceptor wherein the metal-ligand complex and photoluminescent energy transfer acceptor are chosen, when the first binding partner binds to the second binding partner, the metal-ligand complex and the photoluminescent energy transfer acceptor are brought in interactive proximity, producing a detectable change in luminescence

Art Unit: 1637

(See pg. 53, lines 6-21). The biomolecule is Human serum albumin (HAS) and anti- Human serum albumin (HAS) (See pg. 8, lines 18-19, pg. 24, lines 16-20).

One of ordinary skill in the art would have been motivated to have biomolecule, such as nucleic acid or protein attached to the metal-ligand particle as taught by Lakowicz because the metal-ligand complex works as a biomolecular probe which has high sensitivity and specificity and is valuable in biochemistry and biophysics (See pg. 13, lines 20-22). It would have been prima facie obvious to attach the biomolecules, such as nucleic acid or protein to the metal-ligand particle to make the instant invention.

Summary

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/073,625

Page 7

Art Unit: 1637

Joyce Tung *J.T.*
October 18, 2005

K. R. Horlick
KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

10/20/05